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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

|                                       |   |                    |
|---------------------------------------|---|--------------------|
| IN RE: FOSAMAX PRODUCTS               | ) |                    |
| LIABILITY LITIGATION                  | ) |                    |
| _____                                 | ) | MDL NO. 1789       |
| <i>This Document Relates to:</i>      | ) | 1:06-md-1789 (JFK) |
|                                       | ) |                    |
| <i>Boles v. Merck &amp; Co., Inc.</i> | ) |                    |
|                                       | ) |                    |
| Case No.: 1:06-cv-094555-JFK          | ) |                    |
| _____                                 | ) |                    |

**JURY INSTRUCTIONS PROPOSED BY  
DEFENDANT MERCK SHARP & DOHME CORP.**

Defendant Merck Sharp & Dohme Corp., formerly known as Merck & Co., Inc., (“Merck”) submits these Proposed Jury Instructions and requests that this Court charge the jury accordingly. Each instruction is submitted as a separate request, and a separate ruling is requested for each instruction. Merck may also submit such supplemental instructions and special interrogatories or withdraw or modify any of these instructions as may be required by further rulings of the Court prior to the trial, the presentation of

evidence during the trial, the filing of proposed instructions by other parties, and any ruling by the Court following the submission of those instructions.

By submitting proposed jury instructions regarding Plaintiff's claims, Merck does not concede that Plaintiff's claims, or any issues relating to those claims, can or should be properly submitted to the jury. In addition, these Proposed Jury Instructions are made without waiving Merck's motions and objections regarding Plaintiff's claims or alleged damages.

**DEFENDANT'S PROPOSED INSTRUCTION NO. 1**

**Roles of the Court and the Jury**

**MEMBERS OF THE JURY:**

You have now heard all of the evidence in the case, as well as the final arguments.

It becomes my duty, therefore, to instruct you on the rules of law that you must follow and apply at arriving at your decision in this case.

In any jury trial, there are, in effect, two judges. I am one of the judges; the other is you, the jury. It is my duty to preside over the trial and to determine what testimony and other evidence is admissible under the law for your consideration. It is also my duty at the end of the trial to instruct you on the law applicable to the case.

You, as jurors, are the judges of the facts. But in determining what actually happened in this case – that is, in reaching your decision as to the facts – it is your sworn duty to follow the law I am now in the process of defining for you and you must follow my instructions completely. You have no right to disregard or give special attention to any one instruction, or to question the wisdom or correctness of any rule I may state to you. That is, you must not substitute or follow your own notion or opinion as to what the law is or ought to be. It is your duty to apply the law as I give it to you, regardless of the consequences.

By the same token, it is also your duty to base your verdict solely upon the testimony and other evidence in the case without prejudice or sympathy. That was the promise you made and the oath you took before being accepted by the parties as jurors in this case, and they have the right to expect nothing else.

Authority: *Boles I*, written charge at 1-4.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

**DEFENDANT'S PROPOSED INSTRUCTION NO. 2**  
Corporate Parties

This case should be considered and decided by you as an action between persons of equal standing in the community, of equal worth, and holding the same or similar stations in life. All persons and corporations stand equal before the law and are dealt with as equals in the court of justice.

Authority: *Boles I*, written charge at 5.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

### **DEFENDANT'S PROPOSED INSTRUCTION NO. 3**

#### **Evidence**

As I stated earlier, it is your duty to determine the facts, and in doing so, you must consider only the evidence I have admitted in the case. The term "evidence" includes sworn testimony of the witnesses and the exhibits admitted into the record.

Remember that any statements, objections, or arguments made by the lawyers are not evidence in the case. The function of the lawyers is to point out those things that are most significant or most helpful to their side of the case, and in doing so to call your attention to certain facts or inferences that they are particularly concerned that you recall. In the final analysis, however, it is your own recollection and interpretation of the evidence that controls in this case. What the lawyers say is not binding upon you and is not evidence.

Also during the course of the trial, I have occasionally made comments to the lawyers, or asked a question of a witness, or admonished a witness concerning the manner in which he or she should respond to the questions of counsel. Do not assume from anything I may have said that I have any opinion concerning any of the facts in this case. In arriving at your findings as to the facts, you should disregard anything that I may have said during the trial as to the facts of the case. If you did construe any of my remarks during the course of this trial, however, as a comment on the evidence, or its weight, I instruct you that any such comment on my part as to the facts should be disregarded by you entirely since you, as jurors, are the sole judges of the facts in this case.

While you should consider only the evidence in the case, you are permitted to draw such reasonable inferences from the testimony and the exhibits as you feel are justified in the light of common experience. In other words, you make deductions and reach conclusions that reason and common sense lead you to draw from the facts that have been established by the testimony and evidence in this case.

You may consider either direct or circumstantial evidence. "Direct evidence" is the testimony of one who asserts actual knowledge of a fact, such as eye witnesses. "Circumstantial evidence" is proof of a chain of facts and circumstances indicating a fact to be proved. The law makes no distinction between the weight to be given to either direct or circumstantial evidence.

In deciding this case, you are expected to use good sense. Give the evidence and the testimony of the witnesses a reasonable and fair interpretation in light of your own knowledge of the natural tendencies of human beings. In weighing the testimony and in determining the credibility of any witness, you may consider the conduct of the witness, his or her bearing on the witness stand, his or her personal feelings as demonstrated by his or her testimony and his or her actions, any interest he or she may have in the outcome of the case, any prejudice or bias he or she may have shown, and any partiality he or she may have demonstrated.

If a witness is shown to have testified falsely concerning any material matter, you have a right to distrust such witness' testimony on other matters and you may distrust all of the testimony of that witness. However, you may consider that part of the witness' testimony that you find truthful and credible. That is up to you.

You should keep in mind, of course, that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth as he or she remembers it because people may forget some things or remember other things inaccurately. So, if a witness had made a misstatement, you need to consider whether that misstatement was an intentional falsehood or simply an innocent lapse of memory; and the significance of that may depend on whether it has to do with an important fact or with only an unimportant detail.

The testimony of a single witness may be sufficient to prove any fact, even if a greater number of witnesses may have testified to the contrary, if after considering all the other evidence you believe that single witness. It is not the number of witnesses that should prevail, but the truth and accuracy of the testimony.

Authority: *Boles I*, written charge at 5-13.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 4

### Expert Witnesses

When knowledge of a technical subject matter may be helpful to the jury, a person who has special training or experience in that technical field may be called as an expert witness and is permitted to state his or her opinion on those technical matters. Such witnesses have testified in this case. You are not, however, required to accept that opinion. As with any other witness, it is up to you to decide whether to rely on it.

If you should decide that the opinion of an expert witness is not based upon sufficient education and experience, or if you should conclude that the reasons given in support of the opinions are not sound, or that the opinion is outweighed by other evidence, then you may disregard the opinion entirely.

In deciding whether to accept or rely upon the opinion of an expert witness, you may consider any bias of the witness, including any bias you may infer from evidence that the expert witness has economic, philosophical, or any other interest in the outcome of the case.

Authority: *Boles v. Merck I*, written charge at 13-15.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 5

### Depositions

Certain testimony has been presented to you through deposition. A deposition is the sworn, recorded answers to questions asked to a witness in advance of the trial. Under some circumstances, if a witness cannot be present to testify from the witness stand, that witness' testimony may be presented, under oath, in the form of a deposition. Some time before this trial, attorneys representing the parties in this case questioned witnesses under oath. A court reporter was present and recorded the testimony. [Some of these depositions were videotaped, and have been presented to you via video. Some of the depositions were not videotaped, and the testimony from those depositions has been read to you.] All of the deposition testimony[, regardless of whether it was videotaped,] is entitled to the same consideration, is to be judged by you as to credibility, and weighed and otherwise considered by you insofar as possible in the same way as if the witness had been present and had testified from the witness stand in court.

Authority: *Boles I*, written charge at 15-16 (*as modified*).

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_



## DEFENDANT'S PROPOSED INSTRUCTION NO. 6

### Objections to Evidence

During the course of trial, you heard objections to evidence. Sometimes these have been argued out of the hearing of the jury.

It is the duty of the attorney on each side of a case to object when the other side offers testimony or other evidence which the attorney believes is not properly admissible. You should not draw any inference against or show any prejudice against a lawyer or his client because of the making of an objection.

Upon allowing testimony or other evidence to be introduced over the objections of an attorney, the Court does not indicate any opinion as to the weight or effect of such evidence. As stated before, you, the jury, are the sole judges of the credibility of all witnesses and the weight and effect of all evidence.

When the court has sustained an objection to a question addressed to a witness, the jury must disregard the question entirely and may draw no inference from the wording or speculate as to what the witness would have said if permitted to answer the question. If an answer was stricken, you are to disregard it.

During the course of trial, I have occasionally asked a question of a witness in order to bring out facts not then fully covered in the testimony. Do not assume that I hold any opinion on the facts to which my question or questions may have related. Remember that at all times, you, as jurors, are the sole judges of the facts.

Authority: *Boles I*, written charge at 16-19.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

**DEFENDANT'S PROPOSED INSTRUCTION NO. 7**  
Contentions of the Parties

This lawsuit arises out of Plaintiff Shirley Boles' use of Fosamax. Merck manufactured Fosamax.

Plaintiff contends that she took Fosamax, that Fosamax had a defect in its design, and that this defect caused her to develop osteonecrosis of the jaw ("ONJ") prior to October 2003. Plaintiff seeks compensatory damages for her injury.

Merck contends that the scientific evidence does not establish that Fosamax causes ONJ. Merck also contends that Fosamax did not cause Plaintiff's injuries, and that Plaintiff's injuries were caused by her own independent health risk factors.

Authority: *Boles I*, written charge at 19-22 (*as modified*).

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

**DEFENDANT'S PROPOSED INSTRUCTION NO. 8**

**Burden of Proof**

Plaintiff has the burden to prove each of her claims by the greater weight of the evidence.  
“Greater weight of the evidence” means the more persuasive and convincing force and effect of the entire evidence in the case.

*Authority: Boles I, written charge at 24 (as modified); Florida Standard Jury Instructions in Civil Cases 401.3 (as modified).*

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

**DEFENDANT'S PROPOSED INSTRUCTION NO. 9**  
Design Defect

Plaintiff claims that Merck is liable because Fosamax was defectively designed. To establish Merck's liability for this claim, the Plaintiff must prove the following two elements:

- (1) Fosamax was a defective product due to a defective design; and
- (2) Fosamax's defective design was a "legal cause" of Plaintiff's injury.

A product is defectively designed if the product is in an unreasonably dangerous condition and the product is expected to and does reach the user without substantial change affecting that condition. A prescription drug is "unreasonably dangerous" if the foreseeable risks of the drug outweigh its benefits. In determining whether the foreseeable risk of danger outweighed the benefits, you should consider the feasibility of an alternative safer design given the scientific and technical knowledge that existed at the time of manufacture – in this case, prior to October 2003. You should consider not only the benefits to Plaintiff, but also the overall usefulness and benefits to the public as a whole.

If the Plaintiff does not prove her defective design claim by the greater weight of the evidence, then you must return a verdict in favor of Merck. If the greater weight of the evidence does support Plaintiff's claim, then you must determine if Plaintiff was herself responsible and, if so, whether such responsibility was a contributing legal cause of her injury.

Authority: *Boles I*, written charge at 34-36 (*as modified*); Fla. Stat. Ann. § 768.1257 (in design defect cases, "the finder of fact shall consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of manufacture, not at the time of loss or injury"); *Edic v. Century Products Co.*, 364 F.3d 1276, 1279-80 n.2 (11th Cir. 2004) (it is the "foreseeable" risk that is relevant to strict liability design defect claims); *Sta-Rite Industries, Inc. v. Levey*, 909 So.2d 901, 903-04 (Fla. 3d DCA 2004) (strict liability design defect claim was supported by the evidence because of the "reasonable foreseeability" of the injury); *In re Fosamax Prods. Liab. Lit.*, 2010 WL 12572999, \*6 ("The defectiveness of a design is determined based on an objective standard, not from the viewpoint of any specific user.") (quoting *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999)); *Maxwell v. Howmedica Osteonics Corp.*, \_\_\_ F. Supp. 2d \_\_\_, 2010 WL 1930966, \*4 (N.D.N.Y. May 10, 2010) (when applying risk/benefit test, fact finder is to consider, among other things, "the product's utility to the public as a whole"); *Ramos v. Simon-Ro Corp.*, 2008 WL 4210487, \*8 (S.D.N.Y. Sept. 11, 2008) (same); *Vautour v. Body Masters Sports Industries, Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (risk/benefit analysis includes examining "the usefulness and desirability of the product to the public as a whole").

Given: \_\_\_\_\_  
Given as modified: \_\_\_\_\_  
Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 10

### Government Rules Defense

I will now instruct you on what is known as the "government rules defense." Under the government rules defense, there is a rebuttable presumption that a product is not defective or unreasonably dangerous, and the manufacturer is not liable, if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm complied with required statutes and regulations relevant to and designed to prevent that type of harm that allegedly occurred.

On the other hand, there is a rebuttable presumption that a product is defective or unreasonably dangerous, and the manufacturer is liable, if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm did not comply with required statutes and regulations relevant to and designed to prevent that type of harm that allegedly occurred.

A "rebuttable presumption" is a presumption affecting the burden of producing evidence and requiring the trier of fact to assume the existence of the presumed fact, unless credible evidence sufficient to sustain a finding of the nonexistence of the presumed fact is introduced, in which event the existence or nonexistence of the presumed fact shall be determined by the evidence without regard to the presumption.

Now, before a prescription drug can be sold to patients, the drug must be approved as safe and effective by the FDA. The FDA may not approve a drug unless it finds that the manufacturer has conducted adequate tests showing that the drug is safe for its intended uses. Furthermore, the FDA must also find that the drug is safe and effective for its intended uses each time it approves a new use for the drug.

If you find that Merck complied with applicable FDA regulations at the time Plaintiff took Fosamax, then you must presume that Fosamax was not defective or unreasonably dangerous. It then would be Plaintiff's burden to counter the presumption by presenting credible evidence sufficient to show that Fosamax was defective or unreasonably dangerous. On the other hand, if you find that Merck failed to comply with applicable FDA regulations at the time Plaintiff took Fosamax, then you must presume that Fosamax is defective or unreasonably dangerous, and Merck would bear the burden of rebutting the presumption with credible evidence.

Authority: *Boles I*, written charge at 36-42 (as modified).

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 11

### Causation

In order to prevail in her lawsuit, Plaintiff must show that a defect in Fosamax's design was the "legal cause" of her injury. A defect in design is a legal cause of an injury if it directly and in natural and continuous sequence produces or contributes substantially to producing such injury, so that it can reasonably be said that, but for such defect, the injury would not have occurred.

In order to be regarded as a legal cause of an injury, a defect in design need not be the only cause. Rather, a defect may be a legal cause of an injury even though it operates in combination with the act of another, a natural cause, or some other cause if such other cause occurs at the same time as the defect and if the defect contributes substantially to producing the alleged injury.

A defect in design may also be a legal cause of an injury even though it operates in combination with some other cause occurring later, if the resulting injury was a reasonably foreseeable consequence of the defect and the defect contributed substantially to producing it.

Authority: *Boles I*, written charge at 42-44 (*as modified*).

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 12

### Damages

Now, let me speak with you about damages. "Damages" is the term in dollars and cents that expresses the injuries sustained by the Plaintiff. If your verdict is for Merck on Ms. Boles's claim, you will not consider the matter of damages. If the Plaintiff has proven her claim against Merck, you must determine the damages to which she is entitled.

You should not interpret the fact that I give you instructions about damages as an indication in any way that I believe that the Plaintiff should, or should not, win this case. It is your task first to decide whether the Plaintiff suffered damages as a result of Merck's fault. I am instructing you on damages only so that you will have guidance in the event that you decide Merck is liable and the Plaintiff is entitled to recover money from Merck.

If you decide that Plaintiff is entitled to recover damages, you should determine and write on the verdict form, in dollars, the total amount of injury or damage which the greater weight of the evidence shows she sustained as a result of the incident complained of, including any such damage as she is reasonably certain to incur in the future. You shall consider the following elements: any bodily injury sustained by Ms. Boles, and any resulting pain and suffering, disability or physical impairment, mental anguish, inconvenience, or loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future. There is no exact standard for measuring such damage. The amount should be fair and just in light of the evidence.

If the greater weight of the evidence shows that Plaintiff has been permanently injured, you may consider her life expectancy. The mortality tables received in evidence may be considered in determining how long Plaintiff may be expected to live. Such tables are not binding on you but may be considered together with other evidence in the case bearing on Plaintiff's health, age and physical condition, before and after the injury, in determining the probable length of her life.

Again, the mere fact that I have given you instructions on the law of damages does not in any way suggest that I believe that any damages are due in this case. Whether or not the Plaintiff is entitled to recover and whether or not any damages are due is for you to decide.

Authority: *Boles I*, written charge at 44-48 (*as modified*).

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_



**DEFENDANT'S PROPOSED INSTRUCTION NO. 13**  
Concluding Instructions

It is your sworn duty as jurors to discuss the case with one another in an effort to reach a unanimous agreement, if you can do so. Each of you must decide the case for yourself, but only after full consideration of the evidence with the other members of the jury. While you are discussing the case, do not hesitate to re-examine your own opinion and change your mind if you become convinced that you are wrong. Do not, however, give up your honest beliefs solely because the others think differently or merely to finish the case. Remember, that in a very real way, you are the judges - judges of the facts. Your only interest is to seek the truth from the evidence in the case.

Authority: *Boles I*, written charge at 49-50.

Given: \_\_\_\_\_  
Given as modified: \_\_\_\_\_  
Denied: \_\_\_\_\_  
Withdrawn: \_\_\_\_\_

## DEFENDANT'S PROPOSED INSTRUCTION NO. 14

### Verdict Form

I have prepared a special verdict form for your convenience and to aid you in reaching a unanimous decision. You will take the form with you to the jury room. The verdict must represent the considered judgment of each juror. The verdict must be unanimous.

You will note that the form contains several interrogatories or questions. The answer to each question must be the unanimous answer of the jury. In the space provided below each question, you will find the directions which instruct you either to answer the next question, to answer some other question, or to stop and return to the courtroom with your verdict. You must carefully follow these directions as you complete the form. When you retire to the jury room to deliberate on your verdict, you may take this charge with you as well as exhibits which the Court has admitted into evidence. \_\_\_\_\_, Juror # 1, will be your foreperson. After you have reached your unanimous verdict, your foreperson is to fill in on the form your answers to the questions. Do not reveal your answers until such time as you are discharged, unless otherwise directed by me. You must never disclose to anyone, not even to me, any numerical division on any question.

If you want to communicate with me at any time, please give a written message or question signed by the foreperson to the marshal, who will bring it to me. I will then respond as promptly as possible. I will always first disclose to the attorneys your question and my response before I answer your question.

In your note, you may request to see the exhibits. If you want to see an exhibit, I suggest that you ask for all of them, that way you will be able to find what you are looking for even if you have the wrong exhibit number. If you want any of the testimony read back to you, you may also request that. If you do request to have some testimony read back, please be as specific as possible in your request.

After you have reached a unanimous verdict, you are not required to talk with anyone about the case afterwards. You may now retire to the jury room to conduct your deliberations.

Authority: *Boles I*, written charge at 50-54.

Given: \_\_\_\_\_

Given as modified: \_\_\_\_\_

Denied: \_\_\_\_\_

Withdrawn: \_\_\_\_\_